IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS INC., **Plaintiff,** **v.** **RANIR, LLC and** **CVS PHARMACY, INC.** **Defendant.**	**Civil Action No. 07 CV 3302 (KMK)(LMS)** **ECF FILED** **ORAL ARGUMENT REQUESTED**
MEDTECH PRODUCTS INC., **Plaintiff,** **v.** **DENTEK ORAL CARE, INC.,** **KELLY M. KAPLAN,** **RAY DUANE, and** **C.D.S. ASSOCIATES, INC.,** **Defendants.**	
MEDTECH PRODUCTS INC., **Plaintiff,** **v.** **POWER PRODUCTS, INC.,** **d/b/a/ SPLINTEK,** **Defendant.**	

PLAINTIFF'S OBJECTION TO REPORT AND RECOMMENDATION REGARDING DISPUTED TERMS OF CLAIM 17 OF U.S. PATENT NO. 6,830,051

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Plaintiff Medtech Products, Inc. ("Medtech") objects to the Report and Recommendation Regarding Disputed Terms of Claim 17 of U.S. Patent No. 6,830,051 ("the '051 Patent") of Lisa Margaret Smith, Chief United States Magistrate Judge ("Magistrate Judge Smith") (the "Report") (Docket No. 71) in four very narrow respects.

THE APPLICABLE STANDARD OF REVIEW

In the context of a Report and Recommendation, the Court must "make a *de novo* determination … of any portion of the magistrate judge's disposition to which specific written objection has been made." *Medinol Ltd. v. Guidant Corp.*, 500 F. Supp. 2d 345, 349 (S.D.N.Y. 2007); *Pizarro v. Bartlett*, 776 F. Supp. 815, 817 (S.D.N.Y. 1991); Fed. R. Civ. P. 72(b). This standard of review applies to Reports and Recommendations related to claim construction. *See, e.g., ABP Patent Holding, LLC. v. Convergent Label Technology, Inc.*, 194 F.Supp.2d 1257, 1259 (M.D. Fla. 2002); *Golden Voice Technology & Training, L.L.C. v. Rockwell Firstpoint Contact Corp.*, 267 F. Supp. 2d 1190, 1194 (M.D. Fla. 2003).

BACKGROUND

Medtech and its predecessor-in-interest pioneered the over-the-counter sale of dental protectors – products that are designed to prevent the harmful effects of bruxing and clenching. Medtech sells a dental protector that is the subject of the '051 Patent. Medtech's dental protector is self-fitted without the need for a dental professional. The dental protector is generally comprised of two main components, a base and a preform, that are unitarily bonded together. To self-fit the device, the dental protector is immersed in water hot enough to soften the preform and then dipped into cooler water. The device is inserted into the user's mouth and the impression preform is bitten into just enough to form an impression of the teeth in the impression preform as it cools. The preform conforms to the unique configuration of tooth structure in the user's mouth as it rehardens. The base remains hardened and retains its original shape throughout the heating

and cooling phases of the self-fitting process. After achieving proper fit, the user may use the fitted dental protector on a nightly basis to prevent the detrimental effects of bruxing and clenching.

INTRODUCTION

In its Second Amended Complaint, Medtech alleges that Defendant DenTek Oral Care, Inc. ("DenTek") has, *inter alia*, infringed the '051 Patent. (*See generally* Second Amended Complaint, Docket No. 66). Specifically, Medtech asserts that DenTek has infringed Claim 17 of the '051 Patent, which claims a method for fabricating a dental protector device as follows:

> A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:
>
> a) molding and [sic] appliance base from a resin having a Vicat softening temperature of at least 70° C and a Shore A hardness of at least 80; and
>
> b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

Col. 12:47-56. Notably, it is only the method of fabrication itself that is the subject of the asserted claim in this case, not the product that is fabricated from that method.

Medtech and DenTek initially identified thirteen terms of Claim 17 (the "terms") for the Court to construe, but ultimately stipulated to the definitions of all but the following five terms: (1) "interocclusal appliance," (2) "a resin," (3) "molding over the base," (4) "an impression preform," and (5) "having approximately 30% by weight vinyl acetate" (collectively "the Disputed Terms"). Report, p. 8. On July 13, 2007 and July 20, 2007, Medtech and DenTek filed claim construction statements and responses related to the Disputed Terms. (*See* Docket Nos. 45, 46, 49, and 50). On September 5, 2007, a claim construction hearing (the "9/5/07 Hearing")

was held and during which the Court heard the testimony of Medtech's and DenTek's respective expert witnesses and argument from counsel. (Docket No. 52).

Magistrate Judge Smith issued the Report on October 12, 2007. The recommended definitions for the terms "interocclusal appliance" and "having approximately 30% by weight vinyl acetate" as set forth in the Report are in all respects correct, and Medtech urges the Court to adopt these definitions. *See* Report, pp. 10, 21. Medtech, however, respectfully submits that the Report's definitions of "a resin," "molding over the base" and "an impression preform" place improper limitations on the scope of Claim 17 and/or are at odds with the language of the '051 Patent and the understanding that one of ordinary skill in the art would have of the '051 Patent. Accordingly, Medtech respectfully requests that this Court reject the Report's recommended definitions for the terms "a resin," "molding over the base," and "impression preform," as well as any limitation the Report may place on the manner in which bonding of the base and preform may be achieved[1]. Instead, Medtech urges this Court to adopt Medtech's proposed definitions for the three remaining terms in dispute – definitions which are directly supported by the intrinsic and extrinsic evidence of record in this case – and also to clarify and rule that the Report does not implicitly or explicitly define or limit the methods of bonding the preform to the base.

Medtech respectfully requests that the Court grant oral argument on a date and at a time designated by the Court on Medtech's Objection to the Report and Recommendation Regarding Disputed Terms of Claim 17 of U.S. Patent No. 6,830,051.

[1] Report, pg. 17, fn. 4.

SUMMARY OF OBJECTIONS

1. The recommended definition for the term "a resin" improperly imposes the limitation that "a resin" can only be "thermoplastic" even though the parties, as well as their respective experts, agree that in Claim 17 "a resin" can also be "thermosetting."

2. Even though the claim language itself is devoid of any reference to manufacturing by injection molding or to the physical appearance of a resulting device, the recommended definition of the term "molding over the base" imposes manufacturing specifications and structural requirements that improperly limit the scope of Claim 17.

3. Although bonding methods have not previously been raised or addressed by the parties or the Court and no limitation exists in Claim 17, footnote 4 of the Report could be read to limit improperly the invention to require that the unitary bond between the base and preform be achieved only by one or more of the following: "heating the resin, coating the base with a bonding agent or priming material, or texturing the surface of the base."

4. The definition of the term "an impression preform" should properly omit the Report's limiting phrase "consistent with the remainder of the requirements in Claim 17" in order to conform to the Court's reasoning and intent as stated on Page 20 of the Report because the present construction can be read to improperly incorporate all of the other terms of the entire Claim 17 and their limitations, rather than the Court's intended result of defining the disputed term as "a thermoplastic resin which serves as an impression material" and that definition being later independently modified by the chemical makeup as recited in subpart (b) of the claim.

ARGUMENT

"It is a 'bedrock principle' of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations omitted). Accordingly, "claim construction analysis must

begin and remain centered on the claim language itself, for that is the language that the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.,* 381 F.3d 1111, 1116 (Fed. Cir. 2004) (quoting *Interactive Gift Express, Inc. v. Compuserve, Inc.,* 256 F.3d 1323, 1331 (Fed. Cir. 2001)). The role of claim construction "is neither to limit nor to broaden the claim, but to define, as a matter of law, the invention that has been patented." *Network, LLC v. Central Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2005).

The words of a claim "are generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1313. It is well established that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the relevant art at the time of the invention, i.e., as of the effective filing date of the patent application. *Id*. Unless otherwise compelled, a court should give full effect to the ordinary meaning of claim terms even if the terms are broad. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

The claims, however, are not construed in a vacuum. *Toro Co. v. White Consolidated Indus., Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999). If the ordinary meaning of claim language as understood by a person of skill in the relevant art is not readily apparent, a court may determine the ordinary and customary meaning of the term by looking beyond the claims to the specification of the patent, the prosecution history or the patent, and prior art references cited during the prosecution history of the patent. *Phillips*, 415 F.3d at 1312. In an appropriate case, the specification often is the single best guide to the meaning of a disputed term. *Phillips*, 1303 at 1312.

However, there is a "thin line" between reading a claim in light of the specification and

the well-established principle that the specification cannot import limitations into the claims. *Comark Comm., Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998). If a claim term is readily apparent to one with ordinary skill in the relevant art, then consideration of the specification and the prosecution history is typically limited to confirming whether the ordinary meaning applies or whether the patentee intended to deviate from this meaning. *Interactive Gift Express*, 256 F.3d at 1331. The Federal Circuit has repeatedly recognized that there is a difference between construing a term appearing in a claim, and adding a limitation that is not there in the first place. The former is permissible; the latter is not. *See, e.g., Interactive Gift Express,* 256 F.3d at 1331-32 (citations omitted); *Burke, Inc. v. Bruno Indep. Living Aids, Inc.,* 183 F.3d 1334, 1340 (Fed. Cir. 1999).

It is particularly inappropriate to import attributes of the preferred embodiment portion of the specification into the claims as limitations. *Innova/Pure Water,* 381 F.3d at 1117. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988). "This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification." *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986).

Definitions that arise from extrinsic evidence, such as dictionaries, also may be used but are limited by the intrinsic evidence. *Phillips*, 415 F.3d at 1322. Subsequent Federal Circuit decisions have interpreted *Phillips* to mean that dictionaries may be used in one of two situations. First, dictionaries may be used to confirm the definition supported by the intrinsic evidence. *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1145-46 (Fed. Cir. 2005). Second, it is appropriate to look to dictionaries, including scientific and technical dictionaries, to construe the

ordinary and customary meaning of a word when there is "no suggestion in the intrinsic evidence" that defines a term. *Atofina v. Great Lakes Chemical Corp.*, 78 USPQ2d 1417, 1421 (Fed. Cir. March 23, 2006).

I. The recommended definition for the term "a resin" improperly imposes the limitation that "a resin" can only be "thermoplastic" even though the parties, as well as their respective experts, agree that in Claim 17 "a resin" can also be "thermosetting."

The Report's definition of "a resin" improperly limits the term to "a *thermoplastic* solid or semi-solid substance" when it should include "*thermosetting or* thermoplastic." In the Report, it is recommended that the term "a resin" in Claim 17 should be defined as "a *thermoplastic* solid or semi-solid substance." Report, p. 12 (emphasis added). The Report bases this conclusion on the reasoning that "thermoplastic" is "used either in place of or to modify the word 'resin' numerous times throughout the patent and there is no indication anywhere in the patent that the invention can be created with something other than a thermoplastic resin." Report, pp. 13-14. Medtech respectfully submits that the recommended definition is too narrow and should instead be "a thermosetting[2] or thermoplastic[3] solid or semi-solid substance" in light of the intended functionality of the invention as is described and claimed in the patent as well as is understood by those of ordinary skill in the art.

Notably, Medtech and DenTek agree that in Claim 17, the term "a resin" should include thermosetting and thermoplastic materials. Report, p. 11. For the purposes of claim construction, the parties, instead, disputed only whether the term "a resin" should be further

[2] As the Report acknowledges in footnote 3, "thermosetting" is defined as "[r]elating to a compound that softens when initially heated, but hardens permanently once it is cooled . . . ." This is the characteristic exhibited by the base of the device which softens during manufacturing but hardens thereafter.

[3] The Report defines "thermoplastic" as "of or relating to a compound that can be repeatedly made soft and hard through heating and cooling . . . ." This is the characteristic exhibited by the preform and, in certain circumstances as are described in footnote 5 herein below, may also be exhibited by the base of the device.

limited by the classifications of "organic," "natural," and "synthetic." The Court in its Report properly declined to include the limitations of "organic," "natural," or "synthetic" in its definition of "a resin." Accordingly, Medtech's objection is directed only to the Report's exclusion of "thermosetting" from the construction of the term "a resin" and not the recommended definition in its entirety.

Claim 17 of the '051 Patent uses the term "resin" as a general term to designate two separate resin materials: the resin material used to fabricate the base in subpart (a) of the claim and the resin material used to fabricate the impression preform in subpart (b) of the claim. Claim 17 expressly dictates that the resin material in subpart (a) must have different chemical and physical properties from those of the resin material in subpart (b). Specifically, the resin used for the base described in subpart (a) must have a Vicat softening temperature and a Shore A hardness that are higher than those of the preform described in subpart (b) in order for the device to function as intended during the self-fitting process. The patent recites that initially the device (base and preform) is in a hardened state. When the device (base and preform) is heated in water, the impression preform softens but the base remains hardened. As the preform cools, it rehardens to encase the teeth with which it contacts. The base remains hardened during the cooling phase. If reheated, the preform will again soften and reconform to the shape of the teeth then being encased. Conversely, again the base remains hardened in its original shape and will not deform. This distinction in the attributes of the base and preform is paramount to the invention and dictates that the general term "resin" as used in both subparts (a) and (b) includes both thermosetting resins[4] and also thermoplastic resins[5].

[4] The base does not require the thermoplastic property of being "repeatedly made soft and hard through heating and cooling." *See* Report, p. 13 fn. 3. The thermoplastic characteristic is only necessary to the preform, which requires the ability to be softened to mold to the user's teeth. Col. 2:22-24. The base only needs to be softened once when it is initially formed in the manufacturing process. Its very purpose is to retain its rigidity and shape under

That thermoplastic and thermosetting resins are both covered by Claim 17 of the '051 Patent is a conclusion that one of ordinary skill in the art of resins would understand in light of the clear explanation of the hardening and softening characteristics that the resins must exhibit during self-fitting. This conclusion is unchanged by the absence of an express statement in the patent that the word "resin" includes thermosetting resins[6]. First, the accepted meaning and definition of "resin," even as used in commonly accepted dictionaries, includes both thermosetting and thermoplastic materials[7]. Second, Federal Circuit precedent dictates that the description of the preferred embodiment set forth in the Specification should not arbitrarily be interpreted as limiting the scope of the claim, but rather should be viewed as providing an example of at least one embodiment of the invention that falls within the scope of the claims[8].

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temperatures that will soften the preform. *See* Col. 2:26-30; Col. 4:59-64. Accordingly, it is not necessary for the base to be thermoplastic; it could just as simply be permanently hardened after manufacture, the defining characteristic of a thermosetting resin. *See* Report, p. 13 fn. 3.

[5] The base and preform could each be fabricated from thermoplastic resins as long as the thermoplastic resin used for the base has a softening temperature and hardness that meet or exceed those minimum values in subpart (a) of the claim and also exceed the softening temperature and hardness of the thermoplastic resin used to fabricate the corresponding preform.

[6] Claim 17 does not include the words "thermoplastic" or "thermosetting." Any reference to thermoplastic resins is only in the Specification where an example of an embodiment of the invention is described.

[7] The Report relies on the website www.dictionary.reference.com/browse/resin for the definition of "resin." Notably, the American Heritage Dictionary and the American Heritage Stedman's Medical Dictionary exhibited on this webpage explicitly state that the definition of "resin" includes thermosetting and thermoplastic materials and the remaining definitions exhibited there implicitly include thermosetting and thermoplastic in their definitions.

[8] Although a claim should be read in light of the specification, it is particularly inappropriate to arbitrarily import attributes of the preferred embodiment portion of the specification into the claims as limitations. *Innova/Pure Water, Inc.,* 381 F.3d at 1117; *see also Burke*, 183 F.3d at 1341. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." *Laitram Corp.*, 863 F.2d at 865. "This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification." *Texas Instruments*, 805 F.2d at 1563. "Although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." *Acumed, LLC v. Stryker Corp.*, 82 U.S.P.Q.2d 1481, 1485 (Fed. Cir. 2007) (citing *Phillips*, 415 F.3d at 1323) (holding that specification did not limit claim term). The scope of the '051 Patent is not limited to the specific examples or "embodiments" set forth in the '051 Patent, but rather covers all embodiments that satisfy the physical and chemical requirements of Claim 17. Accordingly, the preferred embodiment should be not deemed to exclude thermosetting resins which clearly satisfy the requirements of the claim.

Third, the '051 Patent expressly states that the scope of the patent (as is dictated by the claims) is not limited by the embodiment described in the Specification[9]. Fourth, DenTek's own expert Dr. Rancourt at the 9/5/07 Hearing, acknowledged that the base could be made from thermosetting resins[10]. *See* 9/5/07 Hearing Tr. at p. 136:9-183:9

For these reasons, the recommended definition of "a resin" should be amended to include thermosetting resins as follows: "a thermosetting or thermoplastic solid or semi-solid substance."

II. Even though the claim language itself is devoid of any reference to manufacturing by injection molding or to the physical appearance of the resulting device, the recommended definition of the term "molding over the base" imposes manufacturing specifications and structural requirements that improperly limit the scope of Claim 17.

The Report's definition of "molding over the base" improperly limits the scope of Claim 17 to manufacturing by injection molding and the physical appearance of the resulting device. The Report recommends that "molding over the base" in Claim 17 should be defined as "the step of injecting a thermoplastic resin, the characteristics of which are further defined in 17(b), into an occlusal mold cavity into which the base described in 17(a) has been placed so that the thermoplastic resin becomes an impression preform that covers the space between the side walls

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[9] The '051 Patent expressly disclaims any limitation that may be implied by the description and exemplars shown in the Description section. The '051 Patent states:

> It should be appreciated that the foregoing is merely exemplary and various other and alternate thermoplastic resins may be selected for use in accordance with the invention. The principal rheological and other attributes of the selected resins include a suitable softening temperature range for the impression preform resin which will not create temperature induced discomfort or damage to oral tissue, a softening temperature range and hardness of the base resin such that substantial deformation of the base does not occur during fitting and over prolonged usage.

Col. 10:29-38 (emphasis added). The words "various other" modify the word resin. Thermosetting resins fall within the "various other" types of resins contemplated by the '051 Patent.

[10] Although the Court's Report states that it deems the intrinsic evidence in the '051 Patent sufficient to make a recommendation regarding the disputed terms, it notes that the expert testimony at the 9/5/07 Hearing provided the Court with background on the materials science of resins and the types of resins commercially available. Report, p. 8.

of the base, the inner surfaces of the side walls, and the space above and on top of the horizontal surfaces of the side walls of the base." Medtech respectfully submits that the Court should decline to adopt this definition because it improperly incorporates the limitations of injection molding and structure.

A. Injection Molding Limitation is Improper.

The recommended definition for "molding over the base" improperly limits the fabrication process of the invention to "injection molding." The Report concludes that "incorporating the process of injecting the impression preform resin into a mold that already contains the base into the definition of 'molding over the base' is appropriate," for two reasons: "[1] the ***parties discussed*** the process of injection molding with the Court at the Markman hearing and [2] ***the preferred embodiments describe*** using injection molding to mold the impression perform over the base." Report, p. 17. Neither reason is appropriate to limit Claim 17. Accordingly, Medtech respectfully submits that the recommended definition should not be adopted because it imports limitations on the manufacturing process from the Specification and its exemplary embodiment.

The Report's requirement that the term "molding over the base" dictates that a particular type of manufacturing is required by Claim 17 – namely that Claim 17 requires that only "injection molding" may be used to the exclusion of any other manufacturing or fabrication process – is unsupported by the intrinsic and extrinsic evidence in this case, as well as Federal Circuit precedent[11]. *See* Report, p. 17 ("injecting a thermoplastic resin . . . into an occlusal mold

[11] It is well-settled that patents, and the claims contained therein, are not intended to be manufacturing specifications or production documents. *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1562 (Fed. Cir. 1987), *vacated on jurisdictional grounds,* 486 U.S. 800 (1988), *and cited with approval on remand,* 870 F.2d 1292 (7th Cir. 1989); *see also CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1339 (Fed. Cir. 2003); *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 614 F. Supp. 1278, 1302 (S.D.N.Y. 1985), *aff'd on point, vacated in part on other grounds*, 781 F.2d 198 (Fed. Cir. 1986) ("There is no need for a manufacturing specification."). "Patents are not production documents, and nothing in patent law requires that a patentee must disclose data on how to mass-produce

cavity").

The Report states that it bases its recommendation on the parties' discussion of injection molding at the 9/5/07 Hearing and the Preferred Embodiments section of the '051 Patent. Report, p. 17. However, Medtech did not adopt any such limitation on its manufacturing processes at the 9/5/07 Hearing. Also, there are no references to injection molding in the claim at issue. Instead, any mention of injection molding in the '051 Patent is in the Specification of the Patent. Relevant case law cited above supports the conclusion that Claim 17 is not limited by its description of a preferred embodiment (or otherwise) in the Specification. In fact, in this case, the '051 Patent particularly and expressly teaches away from such limitations:

> Since various possible embodiments might be made of the present invention and since various changes might be made in the exemplary embodiments shown herein, without departing from the spirit if the invention, it should be understood that all matter herein described or shown in the accompanying drawings should be interpreted as illustrative and not in a limiting sense.

'051 Patent, Col. 10:61-67. Accordingly, it is improper to import "injection molding" from the exemplary embodiments into the definition of "molding over the base."

Other manufacturing or fabrication processes may be used to achieve the invention. As acknowledged by Dr. James Rancourt, DenTek's own expert witness at the 9/05/07 Hearing, the impression preform could be molded over the base through any number of molding techniques, not just injection molding. 9/5/07 Hearing Tr. at p. 142:9 – p. 147:18. For example, Dr. Rancourt testified that an impression preform could also be fabricated simply by inserting the resin material into any two-piece mold and then closing the mold. *Id*. Therefore, discussing at oral argument one manufacturing process should not be to the exclusion of the others mentioned.

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the invented product, in patents obtained on either individual parts of the product or on the entire product." *Christianson*, 822 F.2d at 1562. Moreover, "the law requires that patents disclose inventions, not mass production data, and the patents enable the practice of inventions, not the organization and operation of factories." *Id*.

The preferred embodiments should not limit Claim 17. There are no references to injection molding in Claim 17. Claim 17 does not claim or place any limitations on the process by which the base or preform may be molded. Nowhere in the '051 Patent is injection molding stated to be the only way to mold the device. Rather, injection molding is described as an example of one way that the device may be manufactured in the Description section of the Specification. Claim 17 is not limited by its description of a preferred embodiment (or otherwise) in the Specification.

Merely describing an example of the invention is not limiting on Claim 17[12]. In fact, to adopt such a limitation is improper in this case. The Federal Circuit instructs that it is particularly inappropriate to import attributes of the preferred embodiment portion of the specification into the claims as limitations. *Innova/Pure Water*, 381 F.3d at 1117; *see also Burke*, 183 F.3d at 1341. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." *Laitram Corp.*, 863 F.2d at 865. "This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples

[12] There is a "thin line" between reading a claim in light of the specification and the well-established principle that the specification cannot import limitations into the claims. *Comark Comm.*, 156 F.3d at 1186-87; *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed. Cir. 2003). If a claim term is readily apparent to one with ordinary skill in the relevant art, then consideration of the specification and the prosecution history is typically limited to confirming whether the ordinary meaning applies or whether the patentee intended to deviate from this meaning. *Interactive Gift Express*, 256 F.3d at 1331; *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1179 (9th Cir. 2006) (holding that district court improperly imported limitations from specification when interpreting claim term). The Federal Circuit has repeatedly recognized that there is a difference between construing a term appearing in a claim, and adding a limitation that is not there in the first place. The former is permissible; the latter is not. *See, e.g., Interactive Gift Express,* 256 F.3d at 1331-32 ("in looking to the specification to construe claim terms, care must be taken to avoid reading limitations appearing in the specification . . . into [the] claims") (citations omitted); *Burke*, 183 F.3d at 1340 ("Consistent with the principle that the patented invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history."); *Laitram Corp. v. NEC Corp.,* 163 F.3d 1342, 1348 (Fed. Cir. 1998) ("interpreting what is meant by a word and a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper"). In *Liebel-Flarsheim Co. v. Medrad, Inc.*, the Federal Circuit noted that the key to looking to the specification is to view it "without unnecessarily importing limitations from the specification into the claims." 385 F.3d 898 (Fed. Cir. 2004) (citations omitted). "These two rules lay out the general relationship between the claims and written description." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998).

in the specification." *Texas Instruments*, 805 F.2d at 1563. "Although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." *Acumed, LLC v. Stryker Corp.*, 82 U.S.P.Q.2d at 1485 (citing *Phillips*, 415 F.3d at 1323) (holding that specification did not limit claim term).

For these reasons, Claim 17 should be construed without any limitation on the manner in which the base or preform are molded, fabricated or manufactured.

B. Structural Limitation is Improper.

Medtech also submits that the recommended definition for "molding over the base" also improperly incorporates structural limitations into Claim 17. Specifically, the Report asserts that the definition should require the molding process to result in a preform that "covers the spaces between the side walls of the base, the inner surfaces of the side walls, and the space above and on top of the horizontal surfaces of the side walls of the base." Report, p. 16. The Report bases the adoption of such a structural limitation on (1) the section entitled "Summary of the Invention" and (2) the illustrations contained in the Preferred Embodiment section. Report, p. 17. However, neither of the stated reasons support the structural limitations. Notably, the Court expressly found that to incorporate structure into the claim was improper when it construed the term "an impression preform." Report, pp. 19-20[13]. Accordingly, Medtech submits that this Court should adopt Medtech's definition for "molding over the base" as "the step of forming the impression preform of the appliance into a shape on top of the appliance base."

[13] As noted by the Court in its Report where it recommends a definition for "an impression preform," it also is inappropriate to incorporate structural subparts into Claim 17 that are found in other claims of the '051 Patent. The Court specifically states, "there is no indication that Claim 17 was meant to incorporate the structural description of the impression preform as it is stated in Claims 1 and 13, and there is no indication that Claim 17 was meant to be dependent on Claims 1 and 13 . . .Accordingly the fact that Claim 1 and 13 are referenced in other claims and are not referenced in Claim 17 gives rise to the presumption that the limitations – the structural descriptions –include in Claims 1 and 13 were not intended to be present in Claim 17." Report, pp. 19-20.

(1) The Summary is not a proper basis for imposing structural limitations on Claim 17.

The Summary is part of the Specification section of a patent. It is simply "a brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention" and precedes the detailed description of the invention. 37 C.F.R. § 1.73. The summary "should be commensurate with the invention as claimed and any object recited should be that of the invention as claimed." *Id*. The Summary in the '051 Patent complies with 37 C.F.R. § 1.73 because it jointly summarizes the claims directed to the structure of the device (Claims 1-16) and the claim directed to the method by which the device is manufactured/fabricated (Claim 17). Thus, because the '051 Patent claims both the structure of the device in Claims 1-16 and the method of manufacturing the device in Claim 17, the Summary of the '051 Patent must necessarily include a summary of the structure of the device when it also recites the manner in which that device is made.

Medtech respectfully submits that the Report improperly relies on the Summary to impose certain structural requirements on the shape of the base – namely that it must have side walls with horizontal surfaces that can be covered by the impression preform. Likewise, the recommended definition imposes structural limitations on the shape of the impression preform – namely that it must cover the interior side walls of the base and the entire horizontal surface of the base.

These structural limitations are contrary to the language of Claim 17 of the '051 Patent. Of significance is the fact that there is not a single reference in Claim 17 to the structural attributes of either the base or the impression preform. Absent those structural requirements being expressly recited in Claim 17, to read them in from the Summary or other parts of the Specification is improper. *See Interactive Gift Express,* 256 F.3d at 1331-32 ("in looking to the

specification to construe claim terms, care must be taken to avoid reading limitations appearing in the specification . . . into [the] claims") (citations omitted); *Laitram Corp. v. NEC Corp.,* 163 F.3d 1342, 1348 (Fed. Cir. 1998) ("interpreting what is meant by a word and a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper").

Furthermore, the recommended definition does not consider that Claim 17 teaches only that the interocclusal appliance is formed by molding an impression preform over a base in such a manner as to create a unitary appliance. Col. 2:15-16; Col. 12:51-57. Claim 17 does not teach that the shape of the preform is determined by the shape of the base. Rather, "molding over the base" teaches that the shape of the preform is determined by the shape of the mold. *See* 9/5/07 Hearing Tr. at p. 146:10-22. The preform will assume whatever shape is dictated by the shape of the mold from which it is made. This conclusion was supported by the testimony of DenTek's own expert Dr. Rancourt at the 9/5/07 Hearing. At the 9/05/07 Hearing, Medtech's counsel introduced a hand-drawn diagram that demonstrated examples of three different molds (and accordingly three different shapes of the claimed invention) that could be used to shape the preform. This document was entered into evidence as Exhibit 1 to the 9/5/07 Hearing. As acknowledged by Dr. Rancourt, the diagram shows at least two possible configurations of a mold whereby the preform would not cover the entire horizontal face of the base. *See* 9/5/07 Hearing Tr. at p. 146:23 – p. 149:16. Dr. Rancourt specifically confirmed that at least these two mold configurations would create a preform that does not cover the entire interior side walls and/or all horizontal surfaces of the base:

> Q: And on the top one, if we were to remove the device from the mold, wouldn't, in fact, the preform material not cover the walls of the base?

> Dr. Rancourt: It would cover up to and beyond the top edges of the walls, not over the top surface of what form the walls of the base layer.
>
> The Court: I'm sorry, say that again. It would cover - -
>
> Dr. Rancourt: The preform material would cover up the interior sidewalls of the base, and the way it is drawn here in Exhibit 1 would continue even higher, but would not cover the very top horizontal surfaces of the base.

9/5/07 Hearing Tr. at p. 148:7-20 and Exhibit 1 thereto.

> Q: And then the last one at the bottom, if we were to remove a product from this interocclusal device mold, wouldn't it, in fact have no preform above the base walls, in fact, it would be level with the base walls?
>
> Dr. Rancourt: The way you have drawn this picture, the preform would be up to the top edge of the interior walls of the base layer.
>
> Q: That's correct. So it would not go over the walls?
>
> Dr. Rancourt: As drawn, right, the preform would not go over the top edge of the base.

Id. at p. 149:5-12.

Furthermore, there are numerous other base and preform shapes that would fall within the scope of Claim 17. For example, there is nothing in Claim 17 that prohibits the base from having a flat horizontal surface that did not contain a groove or indentation. In such a case, it would be impossible for a preform to cover the entirety of the interior side walls because no such walls would exist. This, however, would not prevent a preform from being molded over this base. Claim 17 also contemplates that the preform could cover less than all of the surface of the mold. A mold could be configured that would render a preform that rested on only a portion of the horizontal surface. Claim 17 only requires that the preform must be molded over at least some portion, but not all, of the base and that the base and preform bond.

Notably, the variety of permissible shapes that the base and preform may assume and still fall within Claim 17 is further enhanced by the fact that the '051 Patent does not claim any one method of bonding the preform to the base. The Specification even contemplates that primers, bonding agents and texturing may be used to augment the bond:

> In this regard, it should be noted that in the foregoing examples, the surface 38 of the base over which the impression preform resin is molded may include a coating of a bonding agent or priming material or may be textured to augment the bond, all within the context of the present invention.

Col. 10:45-50. Thus, Claim 17 is not limited by any shape or structure of the base or preform.

(2) The Figures or illustrations in the Specification do not impose structural limitations on Claim 17.

As an additional basis for the recommendation that the structure of the device should impose limitations on the claimed method of fabricating it, the Report relies on Figures 1, 4, 5, and 7 of the '051 Patent. However, the '051 Patent includes both apparatus and method claims. Claims 1-16 are apparatus claims which are directed to the structure of the invention. The Description section of the patent describes the apparatus of Claims 1-16 in great detail. The drawings are each associated with and directed to the description of the structure of the apparatus of Claims 1-16. No Figures are referenced in Col. 5, lines 6-12 of the Description section of the '051 Patent where the method of Claim 17 is described. Yet, even if a figure or drawing were associated with the method of producing the device as claimed in Claim 17, the Specification would still not be limiting on Claim 17. Instead, the Specification merely provides an example or embodiment of the invention, at best. In fact, the Federal Circuit has ruled that the Figures in the Specification, like the Description section, are not limiting on the claim: "[A] patent's drawings may illustrate only a preferred embodiment and, therefore, do not limit the patent's claim scope." Donald S. Chisum, 5A *Chisum on Patents* § 18.03[2][c]; *see also Gart v. Logitech,*

Inc., 254 F.3d 1334, 1342 (Fed. Cir. 2002) (noting that "drawings [depicting the preferred embodiment] are not meant to represent 'the' invention or to limit the scope of coverage defined by the words used in the claims themselves").

In the present case, the Figures merely illustrate exemplars of the device and not limitations on the scope of Claim 17. *See* Col. 10:29-30. Indeed, the '051 Patent expressly disclaims any limitations created by the illustrations, stating:

> Since various possible embodiments might be made of the present invention and since various changes might be made in the exemplary embodiments might be made of the present invention and since various changes might be made in the exemplary embodiments shown herein, without departing form the spirit of the invention, it should be understood that all matter herein described or show in the *accompanying drawings* should be interpreted as illustrative and not in a limiting sense.

Col. 10:61-67 (emphasis added). The illustrations, therefore, should not be used to determine the meaning of the term "molding over the base" or to impose structural or other limitations on Claim 17 or the '051 Patent. This Court should adopt Medtech's proposed definition of "molding over the base" which comports with the intrinsic and extrinsic evidence of this case as follows: "the step of forming the impression preform of the appliance into a shape on top of the appliance base."

III. Although bonding methods have not previously been raised or addressed by the parties or the Court, footnote 4 of the Report could be read to improperly limit the invention to require that the unitary bond between the base and preform be achieved only by one or more of the following: "heating the resin, coating the base with a bonding agent or priming material, or texturing the surface of the base."

Footnote 4 of the Report should not be read to improperly limit the invention to require that the unitary bond between the base and preform be achieved only by the included methods. Claim 17 of the '051 Patent does not claim the existence or nonexistence of any particular bonding material or otherwise specify the particular manner in which any bond is achieved by

the base and preform. *See* Claim 17. No such requirement or limitation exists. The Specification does instruct that an important characteristic of the invention is the unitary bond of the preform and the base. *See* '051 Patent, Col. 10:39-44. The '051 Patent states:

> An additional and significant characteristic upon which the selection of resins is predicated is the ability to obtain a unitary molded over bond between the base and the preform/maxillary dentition encasement which is well-suited to withstand the high shear and compression forces generated during bruxing and clenching events.

Col. 10:39-44. The Specification then goes on to acknowledge that the bond between the base and preform may be achieved in many ways in addition to those in which the base and preform structurally fit together or in which the materials of the base and preform chemically bond together:

> In this regard, it should be noted that in the foregoing examples, the surface 38 of the base over which the impression preform resin is molded may include a coating of a bonding agent or priming material or may be textured to augment the bond, all within the context of the present invention.

Col. 10:45-50.

Although the Report recognized that a variety of bonding methods exist, the Report, most likely unintentionally, could be read to create a finite list of suitable bonding methods which would implicitly narrow the scope of Claim 17. Report, pp. 17-18 fn. 4. According to Footnote 4 of the Report:

> Your Honor does not limit the creation of the bond to simply "contacting a heated resin with the entire upper surface of the base," but instead leaves open the possibility that the unitary bond that is formed between the impression preform and the base may be achieved by any one or more of the following: heating the resin, coating the base with a bonding agent or priming material, or texturing the surface of the base, as envisioned by the inventor.

Report, p. 18 footnote 4. This appears to limit the methods of bonding only to those recited in footnote 4 of the Report.

However, the manner in which a bond may be achieved should not be confined to the three examples set forth in the Report. There is no support in the patent or the record for imparting such a limitation. Rather, the '051 Patent merely suggests that the unitary bond achieved by the preform and the base *may* be achieved using a bonding agent, priming material or texturing augmentation:

> In this regard, it should be noted that in the foregoing examples, the surface 38 of the base over which the impression preform is molded may include a coating of a bonding agent or priming material or may be textured to augment the bond, all within the context of the present invention.

'051 Patent, Col. 10:45-51. Using a bonding agent, priming material or texturing augmentation or even a heated resin, as the Report suggests, is not required by the '051 Patent. The contemplated bond between the base and preform could be achieved any number of ways, including but not limited to using different shapes of the base and preform that structurally fit unitarily together or materials that chemically bond. In fact, the '051 Patent does not recite an exhaustive list of the ways that the bond may be achieved, but rather expressly disclaims any such limitation on the bonding agent where it states:

> Since various possible embodiments might be made of the present invention and since various changes might be made in the exemplary embodiments shown herein, without departing form the spirit of the invention, it should be understood that all matter herein described or shown in the accompanying drawings should be interpreted as illustrative and not in a limiting sense.

Col. 10:61-67. The Court, therefore, should clarify that there is no limitation on the manner or type of bonding the preform to the base in Claim 17 of the '051 Patent.

IV. The definition of the term "an impression preform" should properly omit the Report's limiting phrase "consistent with the remainder of the requirements in Claim 17" in order to conform to the Court's reasoning and intent as stated on page 20 of the Report because the present construction can be read to improperly incorporate all of the other terms of the entire Claim 17 and their limitations, rather than the Court's intended result of defining the disputed term as "a thermoplastic resin which serves as an impression material" and that definition being later independently modified by the chemical makeup as recited in subpart (b) of the claim.

The Report's definition of the term "an impression preform" should properly omit the Report's limiting phrase "consistent with the remainder of the requirements in Claim 17." The Report recommends that "an impression preform" be defined as "a thermoplastic resin which serves as an impression material consistent with the remainder of the requirements in Claim 17." Report, p. 19. Medtech respectfully points out that this recommended definition appears improperly to incorporate all other definitions of all other terms (and their limitations) of Claim 17 into "an impression preform." This appears to deviate from the well-established principal that terms within a claim must have certain meanings. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). Broader terms contained in a patent claim are modified by the narrower terms in the claim. In Claim 17, no single term encompasses the limitation of the entire claim. They are not incorporated into the term itself. To do so in Claim 17 would produce the illogical result of incorporating the base and its defining properties in Claim 17(a) into the definition of the impression preform described in Claim 17(b). Col. 12:48-57. It also would incorporate the other limitations discussed previously.

Accordingly, Medtech submits that the clause "consistent with the remainder of the requirements in Claim 17" should be omitted from the construction of the term "an impression preform" and the remainder of the Court's recommended construction be retained so that the term "an impression preform" is construed properly to mean "a thermoplastic resin which serves as an impression material."

CONCLUSION

Medtech encourages the Court to adopt the Report's recommendations as to the construction of the terms "interocclusal device" and "having approximately 30% by weight vinyl acetate," but respectfully objects to the recommended construction for "a resin," "molded over the base," and "an impression preform," as well as any limitation on the manner in which the base and preform are bonded together.

Medtech respectfully requests that the Court grant oral argument on a date and at a time designated by the Court on Medtech's Objection to the Report and Recommendation Regarding Disputed Terms of Claim 17 of U.S. Patent No. 6,830,051.

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Respectfully submitted,

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